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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,061

05/12/2005

Arindam Chatterjee

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25885 7590 06/24/2008

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PATENT DIVISION

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EXAMINER

RODRIGUEZ-GARCIA, VALERIE

ART UNIT

PAPER NUMBER

4161

NOTIFICATION DATE

DELIVERY MODE

06/24/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/535,061	<b>Applicant(s)</b> CHATTERJEE ET AL.	
	<b>Examiner</b> VALERIE RODRIGUEZ-GARCIA	<b>Art Unit</b> 4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 5-14 is/are pending in the application.
- 4a) Of the above claim(s) 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

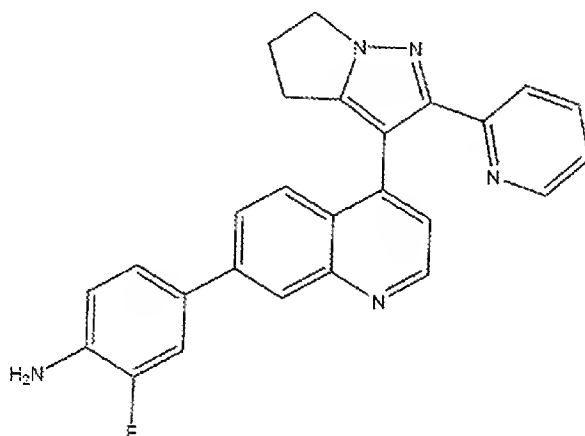
- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/12/05</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Status of the Claims*

Claims 5-14 are currently pending. Claims 1-4 were canceled by applicants.

Applicant's election of Group I, claims 5-13, drawn to compounds and compositions reading on Formula I, in the reply filed on 06/12/08 is acknowledged. The following elected species is also acknowledged: the ditrifluoroacetic acid of



2-Fluoro-4-[4-(2-pyridin-2-yl)-5,6-dihydro-4H-pyrrolo[1,2-b]pyrazol-3-yl]quinolin-7-yl]phenylamine

In response to applicant's election, Group II, claim 14, has been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter. Election was made **without** traverse in the reply filed on 06/12/08.

Claims 5-13 are the subject of this Office Action. This is the first Office Action on the merits of the claims.

***Note***

The species elected by the applicant was not found. The search was extended to a next species.

***Priority***

The earliest effective U.S. filing date has been determined to be 11/21/2002, the filing date of the provisional application 60/428322.

***Claim Rejections - 35 USC § 102***

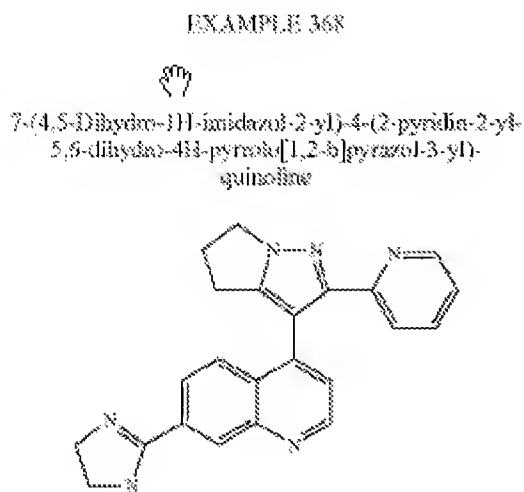
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 5-9, 11 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Sawyer *et al.* (WO 02/094833 with priority filing date of May 24, 2001) and Beight *et al.* (US Patent 7,087,626B2).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 5-9, 11 and 13 recite a compound of the formula I or a pharmaceutically acceptable salt thereof and a pharmaceutical composition comprising a compound of formula I with a pharmaceutically acceptable carrier, diluent or excipient.

Sawyer *et al.* teach the compound:



where  $R_2$  = imidazolyl and  $R_1$  = H (page 223), which is a species of claims 5-9, 11 and 13. Sawyer *et al.* also disclose derivatives, or a pharmaceutically acceptable salt, esters or prodrugs thereof (p. 8, line 24) and a pharmaceutical formulation comprising such compound or pharmaceutically acceptable salt with a pharmaceutically acceptable carrier, diluent or excipient as in claim 13 of the instant application (p. 242, lines 10-15).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 5-13 are rejected under 35 U.S.C. 103(a) as being obvious over Sawyer *et al.* (WO 02/094833 with priority filing date of May 24, 2001) and Beight *et al.* (US Patent 7,087,626B2).

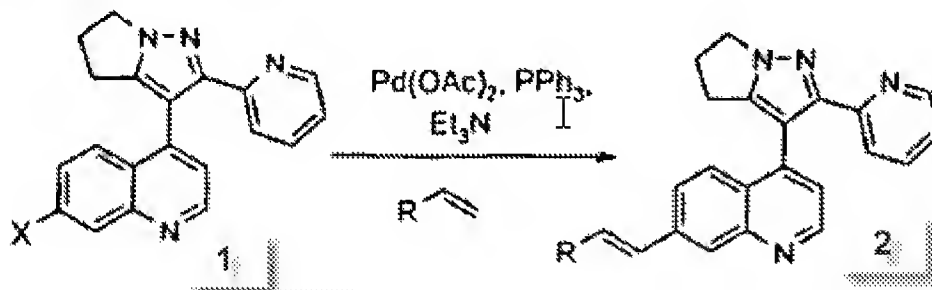
The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and

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reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Sawyer *et al.* teach compounds of structure #1 as their preferred embodiment:

-64-

**SCHEME VII:**

As recited by Sawyer *et al.*, X= halide for the above reaction. One of ordinary skill in the art recognizes the above reaction as a palladium catalyzed reaction. One of ordinary skill in the art would have also envisioned using reactants, besides the here used alkenyl, for common aryl substitutions in palladium catalyzed reactions, such as aryl or heteroaryl reactants in a Suzuki coupling (Suzuki coupling uses boronic acid derivatives). This is mentioned in the disclosure by Sawyer *et al.* (p. 64, lines 4-15) and is cited below:

A skilled artisan would appreciate palladium catalyzed couplings to elaborate the  
5 scope of the invention as shown in Scheme XII.

Aryl substitutions of may be accomplished, through the use of a halo or sulfonyl  
leaving group, X, in combination with a substituted aryl- or heteroarylboronic acid or  
ester in the presence of a suitable palladium catalyst and a suitable base such as potassium  
carbonate as previously described in Scheme III. Another palladium catalyzed reaction,

As such, it would have been prima facie obvious to one having ordinary skill in  
the art at the time the invention was made, to make compounds where X is aryl or  
heteroaryl, as those in claims 5-13, by palladium catalyzed reactions with aryl- or  
heteroarylboronic acid (Suzuki coupling), as disclosed by Sawyer *et al.*

### Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the  
examiner should be directed to VALERIE RODRIGUEZ-GARCIA whose telephone  
number is (571)270-5865. The examiner can normally be reached on Monday-Friday,  
8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's  
supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for  
the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VRG

/Patrick J. Nolan/

Supervisory Patent Examiner, Art Unit 4161